Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Regulatory Directive

DIR2006-03

Confidential Business Information Designation and Segregation Part 1: Submission of Test Data

This Regulatory Directive defines the requirements and procedures for the designation and segregation of confidential business information (CBI) in test data submitted to Health Canada's Pest Management Regulatory Agency (PMRA) under the new *Pest Control Products Act* (PCPA 2002).

It replaces Regulatory Proposal PRO2005-03, *Confidential Business Information Designation and Segregation Part 1: Submission of Test Data,* published for comment in September 2005. Comments received were taken into consideration in finalizing the procedures described in this Regulatory Directive.

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Foreword

Under the authority of the PCPA 2002, the public may inspect test data submitted by registrants in support of a decision made under the Act to register a pest control product, to amend a registration or to continue a registration following a re-evaluation or special review.

The PCPA 2002 also requires that CBI, as defined in the Act, be protected from all forms of public access. To allow for the protection of CBI within test data submitted to the PMRA, they must be designated as CBI by the information provider and accepted as meeting the definition of CBI by the PMRA prior to the registration decision being rendered under the PCPA 2002. This Regulatory Directive addresses the need to define the procedures for designation and segregation of CBI in test data submitted to the PMRA.

The requirements for designation and segregation of CBI for test data provided prior to the PCPA 2002 coming into force is found in Regulatory Directive DIR2006-04, *Confidential Business Information Designation and Segregation Part 2: Previously Provided Test Data.*

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1.0 Definitions

1.1 *Pest Control Products Act* 2002

The PCPA 2002 is an Act to protect human health and safety and the environment by regulating pest control products. It replaces the *Pest Control Products Act*, chapter P-9 of the Revised Statutes of Canada, 1985.

1.2 **Confidential business information (CBI)**, as defined by the PCPA 2002, is information that:

- is designated as CBI by the information provider; and
- concerns information related to the following:
    - manufacturing or quality control processes relating to a pest control product; or
    - methods for determining the composition of a pest control product; or
    - the monetary value of sales of pest control products and other financial or commercial information provided pursuant to the PCPA 2002 or the Regulations; or
    - the identity and concentration of the formulants and contaminants in a pest control product, other than those considered to be of health or environmental concern that are identified on a list to be made available to the public.[1]

1.3 **Test data**, as defined by the PCPA 2002, are:

- scientific or technical information respecting the health or environmental risks or the value of a pest control product.

1.4 **Confidential test data (CTD)**, as defined by the PCPA 2002, are:

- test data that may be protected from disclosure under the *Access to Information Act*.

1.5 The **Register of Pest Control Products (Register)** is:

- a body of pest control product information to which the rules of access of the PCPA 2002 apply. The information the Register must contain is prescribed in subsection 42(2) of the PCPA 2002 and the Regulations.

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[1] The *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and Explanatory Note are available in the *Canada Gazette*, Part II, Vol. 139, No. 24, page 2641.

1.6 **The XML e-Index** is:

- a list, in XML (Extensible Mark-up Language) format, that is an index of test data submitted to the PMRA. The XML e-Index can be compiled by using the e-Index Builder Application (available on the PMRA website).

2.0 Background

2.1 Overview

Increased transparency of the pesticide regulatory system is a fundamental principle of the PCPA 2002. It allows the public to have access to reports on the evaluation of pesticide products and to inspect the test data on which the evaluations were based.

The PCPA 2002 also requires that a register of Pest Control Products be established. The Act specifies what information about pest control products is to be placed in the Register, at what time the information is to be placed in the Register and how access to the information is to be granted to the public. (See subsection 42(2) of the PCPA 2002). The test data supporting the registration decision are placed in the Register following the registration decision. Once test data are placed in the Register, they are to be made accessible for public inspection under controlled conditions. The conditions set out in the PCPA 2002 include the submission of an application to inspect the test data and a signed affidavit made under oath or statutory declaration made under the *Canada Evidence Act*, stating the purpose of the inspection and that the person does not intend to use the test data or make them available to others in order to register or amend a pest control product in Canada or elsewhere.

The registration decisions to which the provisions for public inspection of test data apply include those concerning new and amended registrations and decisions made upon completion of re-evaluations and special reviews.

The PCPA 2002 also requires protection of Confidential Business Information (CBI), as defined in the Act, from all forms of public access. For the purpose of protecting CBI from public inspection, CBI within test data submitted to the PMRA must be designated as CBI by the information provider and accepted as meeting the definition of CBI by the PMRA prior to issuing the registration decision under the PCPA 2002. If the PMRA determines that information designated as CBI does not meet the definition of CBI as defined in the PCPA 2002, then it is not CBI. The PMRA is required by the Act to give written notice to the information provider stating the reasons why the information is not CBI.

2.2 Relevant Statutory Provisions

The provisions relevant to this document are detailed in Table 2.2.1.

A copy of the PCPA 2002 (Bill C-8) can be accessed at the following address: www.pmra-arla.gc.ca/english/legis/pcpa-e.html. Requests for assistance should be directed to the Pest Management Information Service at 1 800 267-6315 within Canada, at 1 613 736-3799 outside Canada, or via e-mail at pmra_infoserv@hc-sc.gc.ca

Table 2.2.1 PCPA Reference to Requirements

PCPA 2002 Requirement	PCPA Reference
The PMRA shall allow the public access to, and copies of, any information in the Register that is not CTD or CBI.	42(4)
Upon meeting certain requirements, any person may inspect CTD.	43(1)
Definition of CBI	43(4) and 43(5)
CBI must be designated by the information provider.	43(4)
The PMRA has the authority to determine the form and manner in which information is provided.	7(1)
The PMRA decides whether designated information meets the definition of CBI.	43(6)
The PMRA must give written notice to the information provider if it is determined that designated information is not CBI and the reasons for it.	43(7)

3.0 Scope

This policy applies to test data submitted under the PCPA 2002, including test data submitted in support of the following:

- applications to register or amend a pest control product, including joint reviews;
- maximum residue limit (MRL) submissions;
- re-evaluations;
- special reviews; or
- responses to deficiency requests or other requests for information.

NOTE: Data reviews and study summaries are considered test data and will be treated like other test data in accordance with this directive.

4.0 Designation and Segregation of CBI

For CBI to be protected from public access, the information provider must designate and segregate CBI in the manner described hereafter. The CBI must also be accepted by the PMRA as meeting the definition of CBI in the PCPA 2002.

In addition, the information provider may choose to insert a Statement of CBI page in each document indicating whether the document, in its entirety, meets the definition of CBI or if the document contained some CBI that has been removed and placed in a companion CBI Reference document.

To facilitate the protection of CBI in test data, the PMRA requires the following:

- the mandatory use of the CBI field in an accompanying XML e-Index to flag those documents that are CBI;
- a document under DACO (data code) 0.8.11 titled CBI Designation Methodology, indicating whether the designation of CBI has been claimed through use of the XML e-Index CBI field only or by using both the XML e-Index CBI field and the inclusion of a Statement of CBI page in each document (see Appendix II for template);
- the segregation of CBI into a separate CBI Reference document, where a document contains some CBI, but the entire document is not CBI (see Appendix II for example); and
- the document data in the XML e-Index for the parent document and its corresponding CBI Reference document must be identical except for the CBI field (i.e., parent document marked CBI "No" and CBI Reference document marked CBI "Yes").

The PMRA will verify that all documents claimed as CBI (for which the XML e-Index CBI field is set to "Yes") meet the definition of CBI in the PCPA 2002 and that CBI has been segregated appropriately. If the CBI Designation Methodology document indicates that a Statement of CBI page has been inserted in each document submitted, the PMRA will verify that the CBI Statement page and the XML e-Index CBI field match.

4.1 XML e-Index

An XML e-Index must accompany all instances where test data are submitted to the PMRA. Completion of the XML e-Index CBI Field is mandatory for each document; the e-Index Builder Application will not allow you to finalize the XML e-Index without this setting. For more details and guidance on the XML e-Index, see Regulatory Directive DIR2006-05, *Requirements for Submitting Data Index, Documents and Forms.*

4.2 DACO 0.8.11—CBI Designation Methodology Document

The CBI Designation Methodology document is a single signed page that must accompany the data submission and be marked in the XML e-Index as DACO 0.8.11 (See template in Appendix III).

The CBI Designation Methodology document must state one of the following:

> CBI designation has been completed by inserting a signed Statement of CBI page in each document submitted and by using the XML e-Index CBI field.

OR

> CBI designation has been completed using only the XML e-Index CBI field. No verification of any Statement of CBI page is required by the PMRA.

Signatures can be handwritten or electronic, including, but not limited to, graphic representations of cursive signatures, typed free text and digital signatures.

4.3 Segregation

For each document that contains some CBI [e.g., word(s), phrase(s), paragraph(s) or page(s)], the following steps must be taken:

- Extract the CBI from the document (parent), replace it with a reference code and put the excised CBI into a CBI Reference document (see example in Appendix II).
    - The cover page must be titled: CBI Reference document.
    - The cover page must also include identifying information identical to the parent document so that both documents can be linked, e.g., the same laboratory report number, DACO satisfied, author(s), title and report date.
    - Each piece of segregated CBI in the parent document must be replaced by a reference code. The reference code may be determined by the information provider; however, it must be in a format that facilitates identification of excised CBI information with a clear and logical linkage between the parent document and the CBI Reference document.
    - A separate CBI Reference document must be provided for each parent document from which CBI was excised.

NOTE: The two documents, the parent document and the CBI Reference document, must have identical XML e-Index entries except for the CBI field value (i.e., parent document marked CBI "No" and CBI Reference document marked CBI "Yes").

It is only acceptable to segregate information that meets the definition of CBI in the PCPA 2002. Do not remove whole pages unless the entire page is CBI.

4.4 Statement of CBI Page Within Each Document

If the information provider wishes to include the Statement of CBI page in each document and wishes it to be screened by the PMRA during verification of CBI, the CBI Designation Methodology document must state the following:

> CBI designation has been completed by inserting a signed Statement of CBI page in each document submitted and by using the XML e-Index CBI field.

The PMRA will only screen Statement of CBI pages if this statement is in the CBI Designation Methodology document.

When using this option, every document requires a signed Statement of CBI page. If the document is electronic, the signature must be incorporated and displayed in the PDF file. The Statement of CBI must be on a page dedicated for this purpose and located immediately following the title page. If the document has no title page, the CBI Statement must be the first page.

The Statement of CBI page must state one of the following:

- "No claim of CBI is made for any information contained in this document on the basis of the definition of CBI in the PCPA 2002."
- "The entire document is claimed as CBI on the basis of the definition of CBI in the PCPA 2002."
- "Information claimed as CBI, on the basis of the definition of CBI in the PCPA 2002, has been removed to a CBI Reference document."

See Appendix I for an example.

Note that the United States Environmental Protection Agency CBI designation pages can be used, but they must incorporate one of Health Canada's PMRA specific statements mentioned above.

Signatures can be handwritten or electronic, including, but not limited to, graphic representations of cursive signatures, typed free text and digital signatures.

CBI Reference documents do not require a CBI Statement page.

4.5 Summary of Requirements for Each Document

Mandatory			Optional
Document		e-Index CBI Flag	Statement of CBI Page
Contains no CBI		N	No claim of CBI is made for any information contained in this document on the basis of the definition of CBI under the PCPA 2002.
Entire document is CBI		Y	The entire document is claimed as CBI on the basis of the definition of CBI under the PCPA 2002.
Contains some CBI	Parent	N	Information claimed as CBI, as per the definition of CBI under the PCPA 2002, has been removed to a CBI Reference document.
	CBI reference	Y	None
DACO 0.8.11 CBI Designation Methodology		N	None

4.6 PMRA Verification

The PCPA 2002 requires that the PMRA verify the information designated as CBI meets the definition of CBI in the Act. The PMRA will verify CBI has been addressed in the form and manner required and that the designated CBI meets the definition of CBI as defined by the PCPA 2002.

If the optional CBI Statement pages are used in accordance with Section 4.3 of this Regulatory Directive, the PMRA will verify the information on the CBI Statement page matches the designation of CBI provided in the XML e-Index in accordance with Section 4.1 of this Regulatory Directive.

If the PMRA is satisfied that information designated as CBI meets the definition of CBI in the PCPA 2002 and is segregated in accordance with Section 4.2 of this Regulatory Directive, it will be protected from public inspection and the PMRA will acknowledge acceptance of the designated information to the information provider. A data index will

be included indicating the CBI setting in the PMRA document management system for each document provided.

It the PMRA is not satisfied that CBI designation and segregation have been completed in accordance with this Regulatory Directive, the Agency will send a written CBI Notice to the information provider indicating that:

- the information designated as CBI does not meet the definition of CBI in the PCPA 2002; and/or
- the CBI is not segregated in accordance with Section 4.2 of this Regulatory Directive; and/or
- the CBI Statement pages (if that option is used) do not match the XML e-Index CBI flags.

If the CBI Notice requires the information provider to make CBI designations, clarify CBI designations or segregate the CBI in accordance with Section 4.2 of this Regulatory Directive, the PMRA will expect a response to the CBI Notice within 30 days.

- Timeframes may be longer, but CBI must be designated, accepted by the PMRA as CBI and segregated from the test data prior to a registration decision being made. Registration decisions will not be delayed pending CBI designation.

- The CBI Notice will not be treated as a deficiency.

- If CBI has not been addressed satisfactorily by the information provider prior to the registration decision under the PCPA 2002, the test data will be placed in the Register and be subject to public inspection as it was provided.

4.7 CBI Designation for Test Data Previously Submitted to the PMRA

For test data received prior to the day the PCPA 2002 comes into force for which CBI (as defined in the PCPA 2002) has not been addressed in the required form and manner, the PMRA will contact the registrants, prior to the registration decision on the evaluation of the test data, to allow an opportunity to address CBI.

Guidance regarding the requirements and process for addressing CBI for information previously submitted to the PMRA is found in Regulatory Directive DIR2006-04, *Confidential Business Information Designation and Segregation Part 2. Previously Provided Test Data.*

5.0 Implementation

5.1 Upon Publication of this Document

CBI designation and segregation should be addressed in the manner specified in this Regulatory Directive for any test data submitted to the PMRA. This will avoid having to designate and segregate the CBI at a later date per the requirements and process described in Regulatory Directive DIR2006-04, *Confidential Business Information Designation and Segregation Part 2: Previously Provided Test Data*.

5.2 Upon Coming Into Force of the PCPA 2002

CBI must be addressed in the manner specified for all test data provided to the PMRA.

Appendix I

Example Statement of Confidential Business Information

Information claimed as CBI, on the basis of the definition of CBI in the PCPA 2002, has been removed to a CBI Reference document.

Signature

If the document is electronic, the signature must be incorporated and displayed in the PDF file, including, but not limited to, graphic representations of cursive signatures, typed free text and digital signatures.

John Doe, Owner
ABC Chemicals

12 June 2006

Appendix II

Example—CBI Reference Document

CONFIDENTIAL BUSINESS INFORMATION REFERENCE

Parent document:	
Lab. Report No.:	3.141592654
DACO:	4.3.1
Author(s):	John Doe, Jane Doe and Bob Doe
Title:	Short-term Oral Toxicity Study in Rats
Report date:	1999

25 April 2006

CBI Reference
Title: **Short-term Oral Toxicity Study in Rats**

CBI Reference Code	CBI Information Excised	Page Number (line)	Reason for CBI Claim
Examples			
CBI 0001	Propylene glycol	60 (line 20)	Formulant name
CBI 0001	Propylene glycol	71 (line 2)	Formulant name
CBI 0002	Sodium chloride	Throughout document	Formulant name
CBI 0003	Wording for entire paragraph	97	Discloses monetary value

Appendix III

CBI Designation Methodology Document
DACO 0.8.11

Check one of the following:

☐ "CBI designation has been completed by inserting a signed Statement of CBI page in each document submitted and by using the XML e-Index CBI field."

OR

☐ "CBI designation has been completed using only the XML e-Index CBI field. No verification of any Statement of CBI page is required by the PMRA."

Signature

If the document is electronic, the signature must be incorporated and displayed in the PDF file, including, but not limited to, graphic representations of cursive signatures, typed free text and digital signatures.

Name, title
Company

Date dd-Month-yyyy